

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ALL PLAINTIFFS	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PRETRIAL ORDER #190
AGREED ORDER AND STIPULATION REGARDING
PATHOLOGY PROTOCOL FOR PRESERVATION AND TESTING OF EXPLANTS
AND TISSUE SAMPLES TAKEN FROM PLAINTIFFS**

Counsel for the parties having consented hereto,

IT IS on this 12th day of August, 2015, ORDERED that:

1. This protocol governs the preservation, collection, storage, and division of gross and microscopic material purported to contain mesh or any other of Plaintiffs' tissue excised or surgically explanted from Plaintiffs at or near the site of mesh implantation, including but not limited to slides, tissue/paraffin blocks, and gross material (the "Materials"). The Materials related to explanted meshes are potentially unique and important evidence given the claims in cases involving surgical mesh.
2. This protocol applies to all cases in this MDL.
3. With one exception, nothing in this protocol directs healthcare facilities to deviate from normal procedures and policies regarding patient care, pathology processing

and analysis, and specimen retention. The exception is where, in the normal course of business, any healthcare facility would destroy explanted mesh or Materials.

Preservation and Collection

4. Consistent with PTO-121, each Plaintiff will notify the health care facility that takes possession of the explanted Materials at the time of the mesh removal that the Materials should be preserved and that the Materials should be sent to Steelgate, Inc.
 - a. Where Plaintiffs' counsel learns of a Plaintiff's potential revision/explant surgery AFTER the date the surgery occurred, Plaintiffs' counsel must provide the agreed upon Past Surgery preservation notice to the facility (attached as Exhibit A).
Ethicon's attorneys must also be copied on this correspondence.
 - b. Where Plaintiffs' counsel learns of a Plaintiff's potential revision/explant surgery BEFORE the scheduled date of surgery, Plaintiffs' counsel must timely provide the agreed upon Future Surgery preservation notice to the facility (attached as Exhibit B). Ethicon's attorneys must also to be copied on this correspondence.
5. Once a preservation notice has been sent, Steelgate, Inc. will arrange shipment of the Materials to its facility in Florida. Steelgate will then act as a third-party repository of any such Materials.
6. The parties will not interfere with the analysis and preservation of the Materials by the explanting facilities to which any of the Plaintiffs' treating physicians have sent or will send the Materials in the normal course of business.
7. Steelgate will timely notify Plaintiffs and Defendants if and when the Materials are requested from any facility and of obtaining the Materials. The written notification of receipt will include the facility from which the Materials were received, an

itemized inventory of the Materials obtained (including collection date, type of specimen, and source site). Plaintiffs will take all reasonable steps to ascertain collection dates and will notify Defendants immediately upon receipt of this information. Plaintiffs, Defendants, and Steelgate shall document the chain of custody for all the Materials using the form attached as Exhibit C.

8. To the extent that the Materials have already been requested and/or are in possession of Plaintiffs or any of Plaintiffs' representative(s), within forty-five (45) days of the entry of this Order Plaintiffs will provide Defendants with an itemized inventory of the Materials obtained (including collection date, type of specimen, source site, and a precise description of the state of the materials encompassing fixation method (where applicable), a physical description with the dimensions of any explanted material, color copies of any and all photographs of the Materials, information regarding whether they have been altered in any fashion, an accounting of what was received and what remains, etc.), and the name of the facility from which the materials were obtained. Plaintiffs will take reasonable steps to obtain collection date information and will supplement information to Defendants upon receipt. Plaintiffs will then, within sixty (60) days of the entry of this Order, transfer such Materials for storage at Steelgate.

Storage

9. The Materials shall be preserved in a manner that permits the parties equal access and analysis. The fixative used by the explanting health care facility shall be used while the explanted Materials are stored at Steelgate.

10. The parties agree to split the expense of the monthly storage fees incurred by storage of Materials at Steelgate for cases pending in this MDL. Following the division of Gross Specimens in a particular case, each party shall bear its own costs of continued storage of its share of the Materials at Steelgate, if any.
11. Prior to shipping any Materials, Gross Specimens, Slides, or any other pathology to Plaintiff's expert as contemplated in the sections "Division of Gross Specimens" and "Other Pathology" below, Plaintiffs shall notify Defendants of their intention to ship said materials. Plaintiffs must provide the available information contained in Paragraphs 7 and 8 above prior to shipment. Once provided this information, Defendants will have two (2) business days to alert the Plaintiffs prior to shipment of any need to meet and confer based on the state of the materials to be shipped. In the event no agreement can be reached, the parties will seek the Court's guidance.

Division of Gross Specimens

12. For the purposes of this section, "Gross Specimens" are preserved, explanted meshes and/or tissues that have not been processed into tissue/paraffin blocks or histology slides.
13. Each party is entitled to a representative one-half of any Gross Specimens in the exact form as received from the explanting healthcare facility.
14. Division of Gross Specimens will occur in potential trial pool cases no later than three months prior to the deadline for submission of trial pick cases. Outside of potential trial pool cases, Gross Specimens will not be divided in any other case without the agreement of the parties. In the event no agreement can be reached

regarding whether to divide any of the Gross Specimens outside of the trial pool cases, the parties will seek the Court's guidance.

15. Any division of Gross Specimens will be carried out by Plaintiffs' representative(s) with the coordination and input of Defendants' representative(s) to protect Defendants' interest in receiving a representative one-half of the Gross Specimen.
16. Defendants' representatives will have the right to inspect the Gross Specimen and obtain photographs and optical micrographs of the specimen prior to any alteration by or on behalf of Plaintiffs' representative(s), and will have the right to observe, and provide input into, division of the specimen into two comparable and approximately equal samples of mesh and tissue.
17. No tissue will be separated from mesh prior to dividing the Gross Specimen.
18. If the parties cannot agree regarding the manner of division of the Gross Specimen or any portion thereof, the parties will meet and confer in good faith before any division takes place. Neither party will perform any examination, analysis, or testing of the Gross Specimen in any way prior to reaching mutual agreement. In the event no agreement can be reached, the parties will seek the Court's guidance.
 - a. If the amount of the preserved Gross Specimen is such that division in a manner permitting analysis of the mesh and surrounding tissue by both parties is uncertain upon receipt, the parties will meet and confer in good faith. No party will perform any examination, analysis, or testing of the Gross Specimen or alter the Gross Specimen in any way prior to reaching mutual agreement. In the event that no agreement can be reached, the parties will seek the Court's guidance.

- b. If during the course of dividing the Gross Specimen to preserve at least one-half for use by Defendants, the impossibility of providing Defendants with the Gross Specimen useable in the same manner as that intended by the Plaintiffs becomes apparent, the parties will likewise meet and confer in a good faith effort and, if necessary, seek the Court's guidance. Neither party will perform any examination, analysis, or testing of the Gross Specimen or alter the Gross Specimen in any way prior to reaching mutual agreement protocol.
- 19. Following the division of any Gross Specimen into halves that are agreed upon by the parties' representatives present at the division of the Gross Specimen, the parties are free to conduct any testing or analysis on their halves, including destructive testing.

Other Pathology

- 20. Upon receipt, Steelgate will maintain any tissue/paraffin blocks or slides obtained from pathology ("the Slides") in an appropriate manner that effectively preserves them for examination and testing by both parties.
 - a. The tissue/paraffin blocks and/or slides will be stored and maintained by Steelgate until a case is selected as a potential trial pool case. Outside of potential trial pool cases, tissue/paraffin blocks and/or slides will remain in storage at Steelgate, except for Good Cause shown.
 - b. No later than three months prior to the deadline for submission of trial pick cases, the parties will meet and confer regarding retrieval from Steelgate of the tissue/paraffin blocks and/or slides related to the potential trial pool cases.

- c. The apportionment and trading of tissue/paraffin blocks and/or slides will follow the procedure discussed in Paragraph 21 of this protocol. The parties will meet and confer regarding the Plaintiffs' selection of a representative who will be responsible for creating pathology slides from the tissue/paraffin blocks and the procedure for creating such recuts. In the event that no agreement can be reached, the parties will seek the Court's guidance.
 - d. Pathology slides will be created from the tissue/paraffin blocks using standard operating procedures, by or under the direction of the representative selected according to Paragraph 20(c).
21. To the extent that any facility will not release tissue/paraffin blocks and/or slides to Steelgate absent a court order, and to extent either party seeks to request any facility cut additional slides from any tissue/paraffin block for use by their expert(s), the requesting party will ensure that the tissue/paraffin block contains sufficient material to create an equal number of slides for each party. Prior to requesting such slides, the requesting party shall notify the other side and meet and confer regarding the number of slides to be requested and whether the slides will be stained or unstained. The parties will work to complete the meet and confer process such that the slides can be requested from the facility within seven (7) days of the requesting party's notification. Plaintiffs will timely provide Defendants the Slides (including originals and recuts) following Plaintiffs' expert(s) review. Defendants will likewise provide Plaintiffs any recuts reviewed by Defendants' expert(s).

22. This Order specifically authorizes any facility in possession of any Materials for any Plaintiff to provide the Materials to Steelgate when requested, assuming Healthcare Insurance Portability and Accountability Act requirements are otherwise satisfied.
23. This Order does not modify any of the obligations set forth in PTO-121.

ENTERED August 12, 2015


Cheryl A. Hifert
United States Magistrate Judge

APPROVED:

/s/ Benjamin H. Anderson

ATTORNEY FOR PLAINTIFFS
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Cleveland, OH 44113
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/s/ David. B. Thomas

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AND JOHNSON & JOHNSON

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(304) 414-1800

NOTICE TO PRESERVE EVIDENCE
URGENT ACTION REQUIRED

[Date]

Attn: Department of Pathology
[Address of Facility]

Re: [Date of Surgery, Case Caption]

Dear Department of Pathology:

I represent the Plaintiff, Ms. [Plaintiff's last name], and Andy Snowden, copied below, represents the Defendant, Ethicon, Inc. (Ethicon), in the above-referenced lawsuit. There is no litigation pending against your facility or the treating physician in this matter. The pathology and any explanted mesh material is important evidence in the pending litigation and its preservation is critical. I write to request the following:

- **Please verify if any pathology and explant material is available** from Ms. [Plaintiff's last name]'s [date] surgery performed by Dr. [Explant Surgeon], **if so, please continue to preserve using your standard method of preserving pathology and/or explant materials.**
- If a specimen or explant material is available, the parties further request that you contact our explant pathology storage facility representative to arrange for the shipment and storage of these preserved materials once your normal pathology procedures have been completed. Her contact information is as follows:

Kate Grayson
Steelgate, Inc.,
2307 58th Avenue East
Bradenton, Florida 34203
kate@steelgateinc.com
(941) 758-1122 or (866) 647-8335

- In order to facilitate this request, enclosed please find a HIPAA-compliant authorization signed by Ms. [Plaintiff's last name] for the release of the pathology and explant specimens to Steelgate as instructed above.

Instructions for Reimbursement for Costs Incurred

For reimbursement of costs incurred in the collection, preservation, and shipping of the specimens, please submit an itemized invoice to:

[insert Plaintiff's counsel contact info]

Should you have any questions or concerns regarding this matter, please contact either Ms. Grayson or the undersigned.

If you are not the appropriate recipient of this request, please notify and forward a copy of this letter to the appropriate person or entity responsible for ensuring compliance with the terms of this request at your earliest convenience. Thank you very much for your assistance.

Very truly yours,

[Counsel for Plaintiff]
Counsel for Plaintiff

Encls. as stated

cc: Andy Snowden (andy.snowden@butlersnow.com)

Kate Grayson (kate@steelgateinc.com)

NOTICE TO PRESERVE EVIDENCE
URGENT ACTION REQUIRED

[Date]

Attn: Department of Surgery and Pathology
[Address of Explant Facility]

Re: [Date of Anticipated Explant Surgery, Case Caption]

Dear Departments of Surgery and Pathology:

I represent the Plaintiff, Ms. [Plaintiff's last name], and Andy Snowden, copied below, represents the Defendant, Ethicon, Inc. (Ethicon), in the above-referenced lawsuit. There is no litigation pending against your facility or the treating physician in this matter. The pathology and any remaining explanted mesh material is important evidence in the pending litigation and its preservation is critical. I write to request the following:

- **Please follow the pathology procedures your facility uses in the ordinary course of business.** Once you have completed your normal pathology procedures, we request that any pathology, paraffin blocks, and/or pathology slides, as well as any tissues and/or the explanted mesh obtained during Ms. [Plaintiff's last name]'s upcoming surgery, should be preserved by using your standard operating procedures for preserving pathology and explant materials and then shipped to our storage facility, at our expense, as discussed below.
 - Ms. [Plaintiff's last name]'s surgery is scheduled for [date], to be performed by Dr. [Explant Surgeon].
- Please contact our explant pathology storage facility representative to arrange for the shipment and storage of these materials. Her contact information is as follows:

Kate Grayson
Steelgate, Inc.,
2307 58th Avenue East
Bradenton, Florida 34203
kate@steelgateinc.com
(941) 758-1122 or (866) 647-8335

- In order to facilitate this request, enclosed please find a HIPAA-compliant authorization signed by Ms. [Plaintiff's last name] for the release of the pathology and explant specimens to Steelgate as instructed above.

Instructions for Reimbursement for Costs Incurred

For reimbursement of costs incurred in the collection, preservation, and shipping of the specimens, please submit an itemized invoice to:

[insert Plaintiff's attorney contact info]

Should you have any questions or concerns regarding this matter, please contact either Ms. Grayson or the undersigned.

If you are not the appropriate recipient of this request, please notify and forward a copy of this letter to the appropriate person or entity responsible for ensuring compliance with the terms of this request at your earliest convenience. Thank you very much for your assistance.

Very truly yours,

[Counsel for Plaintiff]
Counsel for Plaintiff

Encls. as stated

cc: Andy Snowden (andy.snowden@butlersnow.com)

Kate Grayson (kate@steelgateinc.com)

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____
Law Firm: _____ Surgery Date: _____

ENTRY NO. 1: Pick Up Location / Releasing Party Information

Facility Name: _____
Address: _____
Address: _____

Contact Name: _____ Department: _____

Contact Phone #: _____ Contact Email: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s).

(1) _____ (2) _____

(3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

ENTRY NO. 1: Recipient Location/Receipt information:

Facility Name: Steelgate Inc., 2307 58th Avenue East, Bradenton, FL 34203

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s).

(1) _____ (2) _____

(3) _____ (4) _____

Note any changes of condition:

Condition of specimen: ambient (), frozen (), unfrozen (), refrigerated ()

Condition of Container: undamaged (), damaged (), describe: _____

Person **RECEIVING** Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____
Law Firm: _____ Surgery Date: _____

ENTRY NO. 2: Pick Up Location / Releasing Party Information

Facility Name: Steelgate Inc., 2307 58th Avenue East, Bradenton, FL 34203

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s).

(1) _____ (2) _____

(3) _____ (4) _____

Person **RELEASING** Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

ENTRY NO. 2: Recipient Location/Receipt information:

Facility Name:

Address: _____

Address: _____

Contact Name: _____ Department _____

Contact Phone #: _____ Contact Email: _____

(1) _____ (2) _____

(3) _____ (4) _____

Note any changes of condition:

Condition of specimen: ambient (___), frozen (___), unfrozen (___), refrigerated (___)

Condition of Container: undamaged (___), damaged (___), describe: _____

Person **RECEIVING** Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____
Law Firm: _____ Surgery Date: _____

ENTRY NO. 3: Pick Up Location / Releasing Party Information

Facility Name: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s)).

(1) _____ (2) _____

(3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

ENTRY NO.3: Recipient Location/Receipt information:

Facility Name: _____

Address: _____

Address: _____

Contact Name: _____ Department _____

Contact Phone #: _____ Contact Email: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s)).

(1) _____ (2) _____

(3) _____ (4) _____

Note any changes of condition:

Condition of specimen: ambient (___), frozen (___), unfrozen (___), refrigerated (___)

Condition of Container: undamaged (___), damaged (___), describe: _____

Person **RECEIVING** Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____